IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Abbott Diabetes Care, Inc., *a Delaware corporation*,	)	
Plaintiff,	)	C.A. No. 05-590 (GMS)
v.	)	
DexCom, Inc., *a Delaware corporation*,	)	
Defendant.	)	

DEXCOM, INC.'S REPLY IN SUPPORT OF ITS MOTION TO STRIKE "AMENDED COMPLAINT" AND RENEWED MOTION TO DISMISS COMPLAINT

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I. INTRODUCTION

Abbott describes DexCom as "a small company with limited resources." (D.I. 67 at 20.) That is true. DexCom is "a small company" focused on its own pioneering technologies which enable people with diabetes to continuously monitor their blood-glucose levels. DexCom does have "limited resources" it can devote to patent litigation. Abbott, on the other hand, is a $22.3 billion-per-year industry giant with unlimited resources available for patent litigation. The rules governing patent cases – Article III of the Constitution, the United States Code, the Federal Rules of Civil Procedure, the Patent and Trademark Office Reexamination Regulations, and the Local Rules for the United States District Court for the District of Delaware – serve to ensure a level playing field between parties with such disparate resources. So long as Abbott continues its mission to bully small companies with limited resources, DexCom unapologetically requests that Abbott be required to play by the rules. To that end, DexCom has asked the Court to ensure that it has jurisdiction over this case, requested that the Patent and Trademark Office reexamine the patents-in-suit, and now asks that the Court reject Abbott's arguments that the rules are "technicalities" that should not impede the "practical" pursuit of its business objectives.

Abbott does not dispute that if the Court lacked jurisdiction on August 11, 2005, it lacks jurisdiction today. Abbott ignores the established exceptions to accepting the allegations in a complaint as true, including the exception that legal conclusions like its 35 U.S.C. § 271(e)(1) allegations need not be accepted as true in a complaint. As for its failure to seek leave of court to file its "Amended Complaint," Abbott floats an

argument that Rule 15(a) governs, but is really simply asking the Court to ignore its failure to seek leave under Rule 15(d).

The remainder of the Answering Brief is full of straw man arguments and false *ad hominem* attacks that have no bearing on the merits of this motion. For example, DexCom has never argued for a *per se* rule that there can be no case or controversy absent actual FDA approval. Rather, under the facts of this case, it was uncertain on August 11, 2005, what DexCom product, if any, would eventually be approved by the FDA. Absent that certainty and "immediacy" of a product launch, there was no case or controversy between the parties.[1]

II. ARGUMENT

A. Abbott's "Amended Complaint" Was Governed by Rule 15(d) and Required Leave of Court to File Because It Set Forth Events Which Have Happened Since Its Original Complaint.

Rule 15 is not complicated. Any new pleading that "set[s] forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented" falls outside the scope of Rule 15(a) and inside the scope of Rule 15(d). Fed. R. Civ. P. 15(d). Abbott's "Amended Complaint" sets forth events, such as DexCom's March 27, 2006 FDA approval and subsequent product launch, that clearly happened after the August 11, 2005 date of the original complaint. Thus, Rule 15(d) governs, and leave of court was required.

That some of the new allegations might have occurred before the original complaint does not address the fact that some of the new allegations occurred after the

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[1] Abbott's Answering Brief was due on July 26. As the docket reflects, Abbott did not file and serve its brief until July 27. (D.I. 66.) Nevertheless, DexCom is not seeking to strike the Answering Brief as being untimely. By so doing, however, DexCom is not waiving its right to insist upon the timely filing of future papers by Abbott.

original complaint. Any post-August 11, 2005 allegation triggers Rule 15(d). Here, one of the three newly added patents, the '366 patent, issued on January 24, 2006 – five months after the initial complaint. (D.I. 55 ¶ 13.) Abbott completely ignores the Federal Circuit's *GAF* decision, discussed at length in the Opening Brief, in which the Federal Circuit held that amending a pleading to incorporate the subsequent issuance of a patent falls under Rule 15(d) and requires leave of court. *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 480 (Fed. Cir. 1996) ("GAF amended its complaint in the District of New Jersey to allege that Elk's design patent had issued. GAF did not move for permission to file this supplemental pleading as required by Fed. R. Civ. P. 15(d).").[2] In addition to the '366 patent, other post-August 11, 2005 events, such as the allegations regarding DexCom's March 27, 2006 FDA approval (D.I. 55 ¶ 16), make Abbott's "Amended Complaint" a Rule 15(d) supplemental pleading.

Abbott's failure to seek leave of court was either an oversight or a calculated move to circumvent the Court's authority to decide whether leave should be granted in light of both DexCom's pending motion to dismiss and its pending motion to stay the case during the PTO's reexamination of the four original patents. In its opposition, Abbott neither "fessed up" to an oversight nor advanced a plausible application of Rule 15(a). Thus, one is left with the conclusion that Abbott's failure to seek leave was tactical and not inadvertent.[3]

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[2] Moreover, one cannot infringe a patent that has not yet issued. *See, e.g.*, *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1237 (Fed. Cir. 1985) ("A patent has no retroactive effect."). Thus, Abbott's statement that "DexCom's infringement of the new patents was occurring when Abbott filed its Initial Complaint" (D.I. 67 at 7) is completely false with respect to the '366 patent.

[3] Abbott offers no explanation for why it completely disregarded Local Rule 15.1, which requires that an amended pleading be filed in redline form with the original

Abbott goes on to argue that if Rule 15(d) applies and leave of court is required, such leave should be "freely granted." Although Rule 15(a) provides that "leave shall be freely given when justice so requires," Rule 15(d) permits supplemental pleadings "upon reasonable notice and upon such terms as are just." Neither the Third Circuit nor the Federal Circuit has expanded Rule 15(d) to incorporate Rule 15(a)'s liberal amendment requirements. While some non-binding and secondary authorities cited by Abbott note that policy reasons favor importing Rule 15(a)'s "freely given" standard into Rule 15(d), the Supreme Court, when adopting Rule 15, chose not to put the "freely given" language into Rule 15(d). Thus, the Court need not "freely" grant leave for Abbott's supplemental pleading. Instead, it need only consider whether Abbott's addition of three patents so late in this case amounted to "reasonable notice" to DexCom and the Court.

1. Leave Should Not Be Granted Because DexCom Is Prejudiced By the Addition of Three New Patents Ten Months After the Litigation Began.

DexCom has been prejudiced by Abbott's unreasonable delay in introducing three new patents for a current total of 196 asserted claims. DexCom spent the first ten and one-half months of this litigation studying the original four patents and their file histories, preparing its noninfringement and invalidity defenses, filing reexamination requests with the PTO, and otherwise engaging in time-consuming and expensive litigation tasks.

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pleading attached. Abbott's "Amended Complaint" did not attach the original complaint and did not include a redline version. DexCom was not prejudiced by Abbott's failure to comply with Local Rule 15.1 and, accordingly, is not asking that the Court strike the Amended Complaint on that basis. Nevertheless, DexCom submits that this case will proceed more smoothly if all rules are followed, even if, as Abbott contends, the rules have no "practical effect." (D.I. 67 at 1.)

On the eve of the claim construction process, Abbott added three more patents to this case, two of which issued on May 4, 1999, and October 17, 2000, respectively. Abbott knew about these patents all along, but chose to withhold them until the last minute. Abbott suggests that it was unable to add the three new patents until it received a product sample and other documents from DexCom. But Abbott does not explain how it could determine that DexCom infringed the four original patents without having seen DexCom's product in August 2005, yet could not determine whether DexCom infringed the three new patents until it had received a product sample.[4]

2. Abbott Breached an Agreement Between the Parties and Has Now Waived Any Argument Regarding Prejudice to DexCom.

Abbott has breached an agreement between the parties and should be held to have waived any argument that DexCom is not prejudiced by the addition of the three new patents this late in the case. DexCom outlined the specific prejudice it suffered in its Opening Brief and sought to strike and otherwise dismiss the "Amended Complaint" and its three new patents. Knowing that the Court's busy schedule and crowded docket may not permit the Court to immediately rule on the motion, DexCom and Abbott thereafter jointly agreed to seek a revised scheduling order to encompass the additional patents. But DexCom conditioned its acceptance of that agreement on the parties' mutual promise not to use the agreement as evidence in this case: "in making this request, [DexCom and Abbott] are not in any way prejudicing or waiving their rights concerning any matter in dispute." (D.I. 63 at 1.) The phrase "any matter in dispute" undoubtedly includes DexCom's motion to strike and dismiss the additional patents,

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[4] Upon receiving FDA approval, the DexCom product was readily available to anyone that wanted one.

which was filed before the parties submitted the agreement to the Court. (D.I. 61.) Nevertheless, Abbott has cited the parties' agreement as evidence that DexCom was not prejudiced by the addition of the three new patents: "DexCom's contentions that it would be prejudiced because Abbott amended shortly before claim construction are moot, because the parties agreed to request an extension of certain dates in the scheduling order, including claim construction, and the Court granted this request." (D.I. 67 at 9.)

B. The Court Lacked Jurisdiction Over the Original Complaint and Continues to Lack Jurisdiction Over the Amended Complaint.

Abbott does not dispute that if the Court lacked jurisdiction over the original complaint on August 11, 2005, the Court lacks jurisdiction over the Amended Complaint today. *See, e.g.*, *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634-35 (Fed. Cir. 1991).

1. The Court Lacked Jurisdiction Over the Original Complaint Because There Was No "Immediate" Controversy Between Abbott and DexCom on August 11, 2005.

Abbott invests numerous pages knocking down an argument that DexCom does not advance: namely that FDA approval is required for a finding of a case or controversy. While DexCom's lack of FDA approval was probative of the fact that there was no immediate dispute between the parties, DexCom is not asking the Court to establish a *per se* rule that one must wait until a party gets FDA approval in order to file suit. Rather, DexCom is asking the Court to conclude that any controversy between DexCom and Abbott on August 11, 2005, was not sufficiently "immediate" to satisfy Article III's case or controversy requirement.

Abbott correctly cites the legal standard that the controversy between parties in a declaratory judgment action must be both "real" and "immediate," *see Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997), but Abbott misapplies the term "immediate" to the facts of this case. Abbott selectively points to positive events in DexCom's FDA approval process and leaps to the conclusion that FDA approval was a "foregone conclusion." (D.I. 67 at 14-16.) But if FDA approval was a foregone conclusion, what happened over the next seven and one-half months? Abbott of all companies should know that the FDA approval process is anything but certain. In its last quarterly report filed with the SEC, Therasense, Inc. (the original assignee of the patents-in-suit acquired by Abbott) told its investors that the premarket approval ("PMA") process was "lengthy and uncertain." More specifically it told the SEC:

> The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is complete or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time. Therefore, even if a product is successfully developed, it may not be commercially available for a number of years.

(Therasense, Inc., Dec. 31, 2003 Form 10-K at 31 (attached as Exhibit A).)

DexCom filed its PMA application in March 2005 and, fortunately, achieved a best-case-scenario approval in just over one year. Abbott is still struggling with the FDA to win approval for its competing "Navigator" continuous glucose monitor. In Abbott's annual report covering the period that included the complaint in this case, Abbott told the SEC the opposite story it is telling this Court:

> The process of obtaining regulatory approvals to market a drug or medical device, particularly from the FDA . . . can be costly and time-consuming, and approvals might not be granted for future products on a timely basis, if at all.

> Regulation is not static. The suspension, revocation, or adverse amendment of the authority necessary for manufacture, marketing or sale, and the imposition of additional or different regulatory requirements . . . can also occur.

(Abbott Laboratories, Feb. 21, 2006 Form 10-K at 10 (attached as Exhibit B).) Thus, for Abbott, FDA approval is "lengthy," "uncertain," and "not static." But for DexCom, a small company with limited resources, the FDA approval process was a mere formality in which DexCom "cleared every regulatory step necessary for approval when Abbott filed its Complaint." (D.I. 67 at 15.) While DexCom submits that it is inappropriate to consider the later events to determine whether jurisdiction existed on August 11, 2005, *see GAF*, 90 F.3d at 483, DexCom's failure to get FDA approval for seven and one-half more months is telling.[5] For the reasons set forth in the original motion to dismiss, the Court should conclude that there was no "immediate" dispute between the parties on August 11, 2005. (D.I. 6 at 10-13; D.I. 19 at 2-9.)

2. Even the Authorities Cited by Abbott Compel a Conclusion That There Was Not Sufficient Immediacy and Reality to Warrant Consideration of Abbott's Claim for Declaratory Relief.

Abbott repeatedly relies on *Lang v. Pacific Marine & Supply Co., Ltd.,* 895 F.2d 761 (Fed. Cir. 1990) for the proposition that to find declaratory judgment jurisdiction, "the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a) (1982), or be making meaningful preparation for such activity." *Id.* at 764. But Abbott ignores that under the facts of *Lang*, the Federal Circuit affirmed the finding of no case or controversy. In

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[5] While DexCom did receive FDA approval earlier than expected, Abbott exaggerates this fact. DexCom had stated all along that it had hoped for FDA approval by "Q2 2006," which began on April 1, 2006. (D.I. 67, Ex. C at 1.) The last week of March was not significantly earlier.

Lang, the patents-in-suit covered certain features of a ship's hull. *Id.* at 762. The accused infringer was in the process of building the ship pursuant to designs by Donald Higdon and Associates. *Lang v. Pacific Marine & Supply Co.*, 703 F. Supp. 1404, 1406 (D. Haw. 1989). The complaint for declaratory judgment of infringement was filed while the ship was under construction on April 25, 1998, but the ship was not to be completed until February 1999. *Id.* The Federal Circuit held that there was no case or controversy under those facts because "[t]he accused infringing ship's hull would not be finished until at least 9 months after the complaint was filed." *Id.* at 764. Specifically, the accused infringer did not meet the "immediacy" requirement for an Article III case or controversy. *Id.* at 765.

Here, DexCom's lack of "immediacy" for its product was greater than the shipbuilder's in *Lang*. In that case, at the time of the complaint, the ship was sitting in the shipyard being constructed pursuant to completed designs that required no further approval by regulatory authorities. In DexCom's case, its product was subject to scrutiny and potential change by the FDA. One week before Abbott filed its complaint, DexCom had disclosed to the SEC and its investors that "we do not expect to be able to commercialize our short-term continuous glucose monitoring system or long-term continuous glucose monitoring system before 2006 and 2007, respectively." (D.I. 7, Ex. C at 15.) Even the selective documents cited by Abbott for the proposition that FDA approval was a "foregone conclusion" show that FDA approval was anything but certain. For example, at page 14 of the Answering Brief, Abbott cites a July 25, 2005 DexCom press release for the proposition that there were no deficiencies cited by the FDA at the "100-day meeting" between the FDA and DexCom. (D.I. 67 at 14, Ex. H.)

But that press release expressly states the opposite. Specifically, the FDA notified DexCom at the 100-day meeting that it would be sending DexCom a "Major Deficiency Letter" seeking additional analysis and information. (D.I. 67, Ex. H at 2.) The same press release notes that since the filing of its PMA for the STS sensor, DexCom had "continued to further develop the product platform and underlying technology." (*Id.* at 1.) Thus, whereas the shipbuilder in *Lang* faced no obstacles other than the nine months needed to complete building the ship, DexCom faced seven and one-half months plus continued product development and regulatory hurdles. If the *Lang* case lacked the requisite "immediacy" to satisfy Article III's case or controversy requirement, then DexCom's facts compel the same conclusion.

3. Abbott's Continued Reliance on the "ANDA" Statutory and Regulatory Framework is Misplaced in the Context of This Medical Device Case.

Despite Abbott's denial, every case cited by Abbott in which the court exercised jurisdiction before the accused infringer received FDA approval involved the filing of an Abbreviated New Drug Application ("ANDA").[6] It is not DexCom's classification of

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[6] *See Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1564 (Fed. Cir. 1997) ("Glaxo sued Novopharm . . . seeking a declaratory judgment that Novopharm would infringe the '133 patent under § 271(g) if and when it imported the product following FDA approval of the ANDA."); *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 313 (S.D.N.Y. 2003) (infringement action over ANDA filed by Barr seeking approval to market and sell a generic version of Niaspan); *Glaxo Group, Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1007 (N.D. Ill. 2001) (infringement action over ANDA filed by Apotex seeking approval to market and sell a generic version of Ceftin); *Takeda Chem. Indus. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 399 (S.D.N.Y. 2004) (infringement action over ANDA filed by Watson seeking approval to market and sell a generic version of Actos); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 438 (S.D.N.Y. 2002) ("These infringement actions arise out of Abbreviated New Drug Applications ('ANDAs') filed by Defendants."); *Glaxo, Inc. v. TorPharm, Inc.*, No. 95 C 4686, 1997 U.S. Dist. LEXIS 7260, at *2-*3 (N.D. Ill. May 18, 1997) (Ex. C) ("Glaxo also seeks a declaratory judgment that the product TorPharm intends to manufacture under the ANDA infringes U.S. Letters Patent No. 4,672,133.").

these cases as ANDA cases that is "misplaced" (D.I. 67 at 13-14); rather, it is Abbott's reliance on these ANDA cases that is misplaced. Abbott has not cited a single non-ANDA case in which a product that lacked FDA approval satisfied the requirement "that there is an actual controversy that is both real and immediate." DexCom, on the other hand, cited several non-ANDA cases, like this case, in which the lack of FDA approval was probative of the lack of immediacy. *See, e.g., Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992); *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 214 (D.N.J. 1994) (finding that patentee failed to make a sufficient allegation of immediacy and reality because it was unclear whether FDA would grant defendant's application for license to manufacture accused product); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1289-90 (N.D. Cal. 1991) (dismissing declaratory judgment action regarding implantable defibrillator as premature in light of ongoing FDA review of defendant's medical device), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Benitec Austl. Ltd. v. Nucleonics, Inc.*, No. 04-0174 JJF, 2005 U.S. Dist. LEXIS 22008, at *9 (D. Del. Sept. 29, 2005) (attached as Exhibit D) (dismissing claims because, among other reasons, there was "no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed").

Abbott also erroneously argues that "[c]ontrary to DexCom's position, no court has ever held that there is a special rule for medical device cases – in contrast to pharmaceutical cases – requiring FDA approval for jurisdiction." (D.I. 67 at 12.) First, DexCom is not arguing for a *per se* rule that FDA approval is required for jurisdiction. Second, the courts have recognized that Congress did create a special rule for

pharmaceutical cases (i.e., ANDA cases) by enacting the Hatch-Waxman Act, which authorizes a patent infringement action in the generic pharmaceutical context, despite the absence of a real and immediate case or controversy. The *Glaxo* case relied upon by Abbott recognizes this. *Glaxo v. Novopharm.*, 110 F.3d at 1569 (noting that "§ 272(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity"). That "defined act of infringement" in pharmaceutical cases is the defendant's filing of the ANDA application itself.

In addition to the filing of the ANDA itself being a statutory act of infringement, there are other sound reasons to conclude that an unapproved ANDA could satisfy the case or controversy requirement whereas a similarly unapproved PMA would not. When a drug company files an ANDA, it is seeking to manufacture a generic drug that is identical to a brand name drug. *See generally*, http://www.fda.gov/cder/ogd/#Introduction. Specifically, an ANDA must state that the proposed generic drug and the listed drug are bioequivalent, have the same active ingredient, the same route of administration, the same dosage form, the same strength, and that the labeling and conditions of use prescribed, recommended, or suggested in the labeling be substantially the same. 21 U.S.C. § 355(j). Thus, the first day a generic drug ANDA is filed, the proposed product is well-defined and can form the basis of an infringement analysis. *See, e.g.*, *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification

defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.").

The same is not true for pioneering medical devices like DexCom's continuous glucose monitoring system. *See generally* 21 C.F.R. §§ 812, 814. Unlike ANDA applicants, who are trying to make exact copies of patented drugs, PMA applicants like DexCom are navigating uncharted territory and relying on experimental clinical trials with flexible product designs. A court deciding the immediacy of a patent dispute regarding a generic copy of an existing drug described in an ANDA has certainty about the disputed product, while a court evaluating an unapproved pioneering medical device described in a PMA does not. Thus, cases ruling that an ANDA represents a "real" and "immediate" threat provide no guidance in cases involving a PMA application like this one.

C. Count II of the Original Complaint Failed to State a Claim for Which Relief Can Be Granted Because DexCom's Display at Two Scientific Conferences Was Exempt Under 35 U.S.C. § 271(e)(1).

Abbott claims in its Answering Brief that "DexCom did not dispute that Abbott properly alleged infringement, which in itself moots DexCom's Rule 12(b)(6) arguments." (D.I. 67 at 17.) That is incorrect. DexCom has rigorously and directly contended that Abbott failed to properly allege infringement. First, DexCom argued that Abbott's allegation that "DexCom's manufacture of its product for the purpose of showcasing it at trade shows constitutes an infringing act, not exempted by 35 U.S.C. § 271(e)(1) relating to the collection of information for submission to the FDA" (D.I. 1 ¶ 28), is a "bald assertion" or "legal conclusion" that need not be credited on a motion to dismiss. Second, Abbott's allegation that "[i]n addition to filing its PMA with the FDA,

DexCom has attended at least two trade shows where it has publicized and displayed its product" (D.I. 1 ¶ 16) does not properly allege infringement because "publicizing" and "displaying" a product are not acts of infringement as a matter of law.

1. The Court Need Not Credit Abbott's "Trade Show" Allegations Regarding 35 U.S.C. § 271(e)(1) Because They Amount to Bald Assertions and Legal Conclusions.

DexCom understands the general principle that statements in a complaint are usually accepted as true for purposes of a motion to dismiss. But as DexCom stated in its Opening Brief – and Abbott ignores in its Answering Brief – there are exceptions. Namely, a court need not accept a plaintiff's "bald assertions" or "legal conclusions" as true. *See, e.g.*, *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) ("[A] court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss."). DexCom cited case law supporting its position that Abbott's allegation regarding the "trade show" allegations fit these exceptions. (D.I. 62 at 14-16.) Abbott offers only a conclusory response: "Abbott's allegations must be accepted as true under Rule 12(b)(6)." (D.I. 67 at 18.)

Abbott's allegation in the complaint that DexCom's display of its products at trade shows was "not exempted by 35 U.S.C. § 271(e)(1)" falls squarely within the Third Circuit's exception to the general rule that legal conclusions in a complaint need not be accepted as true. *See In Re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410 (3d Cir. 1997).[7] In that case, the plaintiff alleged violations under Sections 10(b) and

[7] Abbott ignores the Third Circuit authority and instead points the Court to a non-binding Florida decision for the unremarkable proposition that an accused infringer cannot obtain dismissal by contradicting a complaint's allegations with an employee affidavit. *Ventrassist Pty, Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1288 (S.D. Fla. 2005). But in the *Lang* decision repeatedly cited by Abbott, the accused infringer

20(a) of the Securities Exchange Act of 1934 based, in part, on allegedly misleading accounting practices. *Id.* at 1420. Under Third Circuit precedent, such a claim required that the plaintiff prove that the accused accounting practices were "unreasonable." *Id.* at 1417-18. Plaintiffs attempted to satisfy the "unreasonableness" requirement by alleging in the complaint that "defendants had no reasonable basis to state publicly . . . that Burlington Coat Factory would earn between $1.20 to $1.30 per share." *Id.* at 1429 (emphasis added). The Third Circuit, per then-Judge Alito, held that plaintiffs' allegation of "no reasonable basis" amounted to a legal conclusion that need not be credited on a motion to dismiss. *Id.* at 1429-30 ("In asserting that there was 'no reasonable basis' for the November 1, 1993, earnings projection, plaintiffs simply mouth the required conclusion of law."). Likewise, Abbott's allegation that DexCom's activity was "not exempted by 35 U.S.C. § 271(e)(1)" simply mouths the required conclusion of law and could not possibly be stated in more conclusory legal terms.

In addition, in the Third Circuit, an affirmative defense can form the basis of a Rule 12(b)(6) motion to dismiss if it appears on the face of the complaint. *See, e.g.*, *Benak v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 n.14 (3d Cir. 2006); *Official Comm. of the Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, LLP*, 322 F.3d 147, 158 (2d Cir. 2003) ("[A] complaint can be dismissed for failure to state a claim pursuant to a Rule 12(b)(6) motion raising an affirmative defense 'if the defense appears on the face of the complaint.'") (quotation omitted). Because Abbott's

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submitted an affidavit setting forth the projected completion date for the accused ship. *Lang*, 703 F.Supp. at 1406 n.1. The district court relied on that affidavit in concluding that there was no case or controversy, and the Federal Circuit affirmed. *Id.*; *Lang*, 895 F.2d at 764-65. Although DexCom's affidavit was appropriate in this context, the Court need not rely on it to sustain DexCom's motion to dismiss.

description of DexCom's FDA approval activities appears on the face of the complaint (D.I. 1 ¶¶ 12-17, 22, 24, 28), the Court may properly consider DexCom's affirmative defense as part of its Rule 12(b)(6) motion to dismiss. *Id.*

2. "Displaying" a Product at a "Trade Show" Is Not an Act of Infringement as a Matter of Law.

In its Answering Brief, but not in its complaint, Abbott describes the DexCom product displayed at the "trade shows" as "commercially slick" and "glitzy" and claims that DexCom was "simply generating buzz in anticipation of product launch." (D.I. 67 at 18-20.) But even if true, and even if those allegations were in the complaint, those activities would be legally insufficient. *See* 35 U.S.C. § 271. So long as DexCom's making and using of the device fell under the umbrella of seeking FDA approval, its activity was protected under § 271(e)(1), and it could "display" it in any manner it wished without running afoul of the patent laws.

3. The Supreme Court's Holding in *Merck v. Integra* Has No Bearing on This Case.

Abbott criticizes DexCom for not citing the Supreme Court's decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 125 S. Ct. 2372 (2005). But the issue in *Merck* was "whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C. § 271(e)(1)." 125 S. Ct. at 2376. The Supreme Court addressed that issue and gave 35 U.S.C. § 271(e)(1) a broad reading: "the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA." *Id.* at 2383-84 (internal quotation omitted). The Supreme Court's holding in *Merck* has nothing to do

with the insufficiency of the allegations in Abbott's complaint. *Merck* does not hold that Abbott's conclusory legal allegations need be accepted as true or that a court cannot dismiss a premature allegation of patent infringement for lack of case or controversy.

D. If the Court Finds That It Has Declaratory Judgment Jurisdiction Over This Case, the Court Should Decline to Hear It While the Patents-in-Suit are Undergoing Reexamination.

DexCom argued in its Opening Brief that if the Court finds that it has declaratory judgment jurisdiction, it should decline to exercise it because, among other reasons, the four original patents-in-suit are undergoing reexamination at the PTO. Abbott's only response is to attack the reexamination proceeding as "nothing more than run-of-the-mill obviousness arguments based on references that were already considered by the PTO." (D.I. 67 at 22.) Its granting of all four reexaminations indicates the PTO does not agree. DexCom refers the Court to and incorporates its detailed response to this same attack set forth in its reply brief in support of its motion to stay pending reexamination. (D.I. 26, 32, 39, 46, 47, 49.) If the reexamination requests are meritless, the PTO will promptly provide Abbott with favorable rulings, and Abbott can re-file its suit.

E. Abbott's Pages Dedicated to *Ad Hominem* Attacks Have No Bearing on the Merits of DexCom's Motion.

Abbott devotes several pages to criticizing DexCom's "tactical maneuvers" in this case. (D.I. 67 at 1-6, 21-23.) While DexCom would prefer to limit this brief to the merits of its motion, DexCom is forced to respond briefly to the unfounded attacks.

1. Abbott repeatedly describes DexCom's pending motions as "hypertechnical" efforts "to avoid dealing with this matter on the merits." To the extent that DexCom is insisting that Abbott follow the Rules of Civil Procedure and this Court's local rules, DexCom makes no apology for doing so. DexCom agrees that its

limited resources (and the Court's) are best conserved if the reexamination proceedings are completed first, just as Congress said it intended.

2. Abbott claims that DexCom repeatedly denied that its product launch was "imminent." The only relevant date for testing the "imminence" of DexCom's product launch is August 11, 2005 – the date of the original complaint, which is seven and one-half months prior to FDA approval. Perhaps seven and one-half months is "imminent" to a $22.3 billion company, but viewed objectively, seven and one-half months is a long time.

3. Abbott complains that DexCom has "dragged its feet through the discovery process." (D.I. 67 at 22.) To date, DexCom has produced 93,567 documents, and Abbott has produced zero. DexCom began a rolling production of documents on March 7. Abbott has failed to produce a single document in response to DexCom's requests.

4. Abbott's complaint that DexCom "has yet to answer Abbott's contention interrogatories" (D.I. 67 at 4) is perhaps an example of someone drafting the Abbott brief without being cognizant of what else is going on in this case. The Court held a discovery conference with the parties on June 21 – six days before Abbott filed its Answering Brief – and ordered that DexCom need not respond to Abbott's contention interrogatories because they violated the Court's rule that limits the number of interrogatories to 50, including subparts. (D.I. 69 at 11:2-13 ("I am going to order that DexCom need not reply . . . .").)

III. CONCLUSION

DexCom respectfully requests that the Court dismiss the original complaint under Rule 12(b)(1) and 12(b)(6). In the alternative, DexCom requests that the Court strike the Amended Complaint and deny leave to amend. If the Court finds that it has declaratory judgment jurisdiction, DexCom requests that the Court decline to exercise jurisdiction in light of the pending reexamination proceedings at the PTO.

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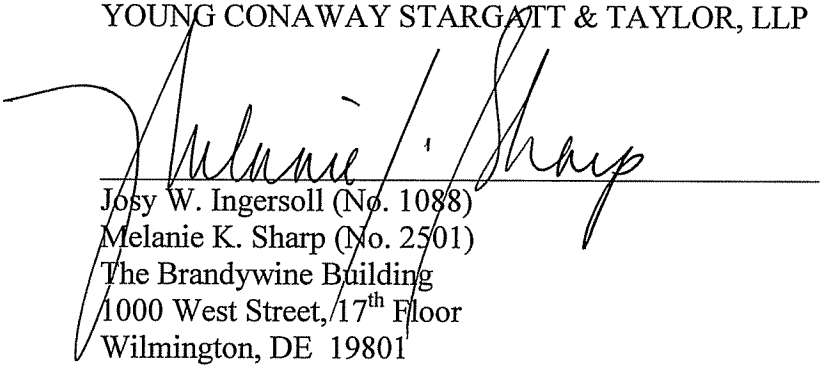

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DATED: August 2, 2006

CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on August 2, 2006, I caused to be electronically filed a true and correct copy of the foregoing document, Dexcom, Inc.'s Reply In Support Of Its Motion To Strike "Amended Complaint" and Renewed Motion To Dismiss Complaint, with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 2, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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